REMARKS

This Amendment is made in response to the Advisory Action mailed January 6, 2011. Claims 19-34 have been cancelled. New claims 35 and 36 have been added and are directed to specific embodiments of the invention. Support for the addition of claims 35 and 36 can be found in the claims and specification as originally filed. Accordingly, claims 1-18 and 35-36 are now pending in this patent application. Entry of the remarks herein and reconsideration and withdrawal of the objections to and rejections of the application are respectfully requested in view of the following remarks.

Claims 1-18 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Action alleges that the data provided by Applicants in support of their claims measures a reduction in gingival bleeding and reduction in supra-gingival plaque, and does not support enablement of "preventing plaque", "preventing plaque build-up" and "preventing gingivitis". In particular, the Action states that only a reduction in bleeding and supra-gingival plaque is supported. Applicants respectfully disagree. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants urge that the key symptoms of gingivitis are bleeding and plaque build-up. It is well known that in order to treat gingivitis; the reduction in bleeding, plaque and plaque build-up are all required. These variables are therefore, the appropriate end-points for prevention claims and are all addressed in the study outlined by Applicants in Example 2. Therefore, the data generated would enable one of skill in the art to conclude, as did Applicants, that the non-aqueous composition is useful for preventing plaque or plaque build-up and for preventing gingivitis. Favorable reconsideration of the rejection under Section 112, first paragraph, is requested.

Claims 1-18 have been rejected under 35 USC §103(a), as being unpatentable over U.S. Patent 5,882,360, granted March 16, 1999, to Gates et al. ("Gates") in view of International Application No. WO 99/13852, published March 25, 1999, in the name of Litkowski et al. ("Litkowski"). According to the Action, Gates teaches a dentifrice containing dentally acceptable abrasives, specifically listing silica, plastic particles, alumina, calcium carbonate, and calcium pyrophosphate as suitable abrasives. Further, the Action states that Litkowski teaches the incorporation of abrasives such as silica, plastic particles, alumina, calcium carbonate and calcium pyrophosphate; and that the bioactive glass can replace all, some, or none of the abrasives (see, for example, page 4, lines 21-29). Based on these disclosures, the Action concludes that it would have been obvious to modify the composition of Gates to include the bioactive glass of Litkowski based on its recognized

suitability for its intended use as both a whitening agent and as an abrasive. Reconsideration and withdrawal of the rejection are respectfully requested.

Gates teaches an anhydrous composition containing an abrasive but does not teach the use of bioactive glass as an abrasive or the use of bioactive glass for the prevention or reduction of plaque, plaque build-up and gingivitis. The Examples of Gates all contain silica as the abrasive component. Litkowski teaches a composition for whitening teeth, which composition contains a bioactive glass and potentially an abrasive; especially preferred is silica (see, page 4, line 25). It does not disclose an anhydrous formulation. Gates' compositions already contain the preferred abrasive of Litkowski, that is, silica. Therefore, a skilled artisan would not have been motivated by the teaching in Litkowski to modify the composition of Gates by using an alternative abrasive. Since Gates was already using the preferred abrasive taught by Litkowski, silica, there is no reason to modify Gates.

The Examiner argues that a prior art reference "is evaluated for **all** that it **reasonably** suggests, and is not limited to preferred embodiments or working examples". The statement in Litkowski, on which the Examiner relies, suggests that bioactive glass may replace all, some or none of the abrasive in a toothpaste formulation. Thus Litkowski presents three options – the third option being the preferred option according to Litkowski – "silica is an especially preferred abrasive for use herein". Litowski provides no disclosure of any particular advantage or surprising activity associated with the inclusion of a bioactive glass as an abrasive (sole or otherwise). Therefore the Examiner's assertion that Litkowski "reasonably" suggests the use of a bioactive glass as an abrasive appears to be without foundation based upon solely an ex post facto hindsight analysis of the present invention, which is not permitted when assessing obviousness.

At best, assuming *arguendo* that one of skill in the art was to have substituted silica with a bioactive glass in Gates' composition, the expectation would be that the composition would whiten teeth. There would have been no expectation that the composition was effective for the prevention or reduction of plaque, plaque build-up and gingivitis. Despite this, the Action suggests that Applicants recognized advantage would flow naturally from the suggestion of the prior art. Specifically, in further support of the obviousness argument, the Action asserts that the use of bioactive glass for the prevention of dental caries and/or gingivitis was known in the art at the time of the invention (as taught by U.S. Patent 6,190,543, granted February 20, 2001, to Stoor et al. ("Stoor")).

Stoor teaches an **aqueous** composition containing preferably 40-80 weight percent of bioactive glass (see, column 3, lines 4-11) for achieving its use. This teaching of such large amounts of bioactive glass would not be commercially viable. As is discussed in paragraphs [0011] through [0013] of the instant published application (US 2007 0264291),

such a composition, which is taught to be applied for prolonged time periods, would have elevated pH levels and would be irritating to the oral tissues. Therefore, one of skill in the art reading Stoor would not have arrived at the instant method which uses an anhydrous formulation with significantly lower amounts of bioactive glass to achieve its efficacy.

Applicants submit that the Examiner must look at the prior art teaching as a whole and cannot pick and choose individual elements from the art in order to arrive at the instant invention. By reading the teaching in the art as a whole, Applicants urge that the instant invention would not have been obvious. Even if Gates and Litkowski provide a non-aqueous bioglass-containing composition, one of skill in the art would not have been motivated by the teaching in Stoor's to modify the amount of bioglass to that claimed herein, particularly since given that teaching, there would be no expectation of success by using the instant composition.

Based upon all of the above distinctions, Applicants urge that Gates and Litkowski, read alone, or in any fair combination, fail to teach or suggest the instant invention. A *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the Section 103 rejection are respectfully requested.

In view of the above remarks, reconsideration of claims 1-18, consideration of new claims 35 and 36, and allowance of this application with claims 1-18 and 35-36 are earnestly solicited.

Respectfully submitted,

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